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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------------|------------------------|
| 10/807,047 | 03/23/2004 | David Feygin | 115-002US | 4801 |
| 22897 | 7590 | 09/17/2007 | | |
| DEMONT & BREYER, LLC 100 COMMONS WAY, Ste. 250 HOLMDEL, NJ 07733 | | | EXAMINER FRISBY, KESHA | |
| | | | ART UNIT 3714 | PAPER NUMBER |
| | | | MAIL DATE 09/17/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/807,047

Applicant(s)

FEYGIN ET AL.

Examiner

Kesha Frisby

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/3/06, 6/27/05, 3/23/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: Please fill in the Statement of Related Cases in paragraph 0001 with the appropriate data.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 1-17 & 19-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Cunningham et al. (U.S. Patent Number 6,470,302).**

Referring to claim 1, Cunningham et al. discloses an apparatus comprising a receiver wherein: said receiver (shaft 44) has at least three degrees of freedom (translation, pitch & yaw), wherein axes of said three degrees of freedom intersect (claim 5); and said receiver receives an end effector (catheter 47), wherein said end effector removably couples to said receiver (Fig. 4 & the associated text).

Referring to claim 2, Cunningham et al. discloses further comprising said end effector, wherein said end effector comprises a catheter (catheter needle assembly 47).

Referring to claim 3, Cunningham et al. discloses wherein two of said three degrees of freedom are rotational (yaw & pitch) and one of said three degrees of freedom is translational (translation).

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Referring to claim 4, Cunningham et al. discloses further comprising pseudo skin (36), wherein said receiver is disposed beneath said pseudo skin (From looking at Fig. 3, the shaft 44 appears to be below/within the case 32).

Referring to claim 5, Cunningham et al. discloses further comprising said end effector (catheter 47), wherein said pseudo skin (4) lies in a plane between said end effector and said receiver, and wherein to simulate a vascular access procedure, said end effector crosses said plane to couple with said receiver.

The examiner takes the same position as in the Written Opinion dated 3/3/06: According to the English dictionary, the definition of the word plane is a surface such that every straight line joining any two points in it lies wholly in it is, or such that the intersection of two such surfaces is always a straight line; the simplest kind of geometrical surface, corresponding among surfaces to the straight line among lines. Hence, in gen. use, an imaginary superficies of this kind in which points or lines in material bodies lie; esp. a horizontal plane of such a kind, a level, as in 'clouds at various planes of elevation.

The plane can then be defined as being a certain level (imaginary superficies) which, in the present case, is lying where the pseudo-skin 36 in fig. 3 of D1 finds itself. It is clear from fig. 3 of D1 that this level divides two areas. The upper one, where the end effector 47 can be found and the lower area (the area below the pseudo skin 36) where the receiver is disposed. The examiner cannot agree with the applicant when he states that it is clear that, in document D1, the receiver shaft 44 extends beyond case 32 and is not below any pseudo skin. In fact, the part which extends beyond case 32 (and also pseudo skin 36) as seen in fig. 3 of D1 is the catheter needle assembly (end effector).

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The receiver part (shaft 44) cannot be seen in fig. 3 of D1 because it is hidden in the case 32. It can, however be seen in fig. 4. where the case 32 has been taken away. Therefore, the examiner is of the opinion that the pseudo skin lies in a plane between said end effector and said receiver; and that, when simulating a vascular access procedure, said end effector crosses said plane to couple with said receiver.

Referring to claim 6, Cunningham et al. discloses further comprising: a plurality of sensors, wherein said sensors: monitor movement of said receiver with respect to said degrees of freedom, wherein said movement is indicative of the position and orientation of said end effector; and generate signals indicative of said monitored movement; and a data processing system, wherein said data processing system receives signals generated by said sensors (column 4 lines 50-54).

Referring to claim 7, Cunningham et al. discloses further wherein said data processing system determines a position and orientation of said end effector based on said received signals (Fig. 1 & column 6 line 45 – column 7 line 35).

Referring to claim 8, Cunningham et al. discloses wherein said receiver comprises a force-feedback assembly (force feedback unit 54), wherein said force-feedback assembly generates a resistance to movement of said end effector (column 10 lines 3-46).

Referring to claim 9, Cunningham et al. discloses wherein said force-feedback assembly comprises a motor (column 10 lines 23-26).

Referring to claim 10, Cunningham et al. discloses an end effector (catheter 47); and a

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movable member (friction wheels 84 & 85 and/or pulleys), wherein: said end effector reversibly couples to said movable member to simulate a vascular access procedure (simulation of vascular access procedures); and said movable member moves along a linear path in response to manipulation of said end effector (Fig. 5B & the associated text).

Referring to claim 11, Cunningham et al. discloses wherein said movable member is coupled to a cable (column 8 lines 42-50).

Referring to claim 12, Cunningham et al. discloses wherein said cable (wire) is coupled to a motor (electric motor).

Referring to claim 13, Cunningham et al. discloses wherein, responsive to a control signal, said motor generates a resistance to movement of said movable member (column 10 lines 3-46 & column 12 lines 40-45).

Referring to claim 14, Cunningham et al. discloses further comprising a plurality of pulleys (pulleys 100, 112 & 115) disposed on a frame (skin traction mechanism 36), wherein: said pulleys engage said cable (belt 108); and said pulleys are arranged so that a tension in said cable aligns with said linear path along which said movable member moves (Fig. 7 & the associated text).

Referring to claim 15, Cunningham et al. discloses wherein said movable member (friction wheels 84 & 85) comprises a pulley (pulleys 100, 112, 114), wherein said movable member is coupled to said cable (belt 108) via said pulley (pulleys 112 & 114).

Referring to claim 16, Cunningham et al. discloses wherein said movable member comprises a magnet (column 12 lines 49-52), and wherein said end effector (catheter

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47) couples to said movable member via said magnet (column 12 lines 40-52).

Referring to claim 17, Cunningham et al. discloses further comprising a housing (housing 50), wherein said movable member is disposed within said housing and said end effector (catheter needle assembly 47) is disposed outside of said housing (Fig. 4 & the associated text).

Referring to claim 19, Cunningham et al. discloses a frame (outside of shaft 44); an arrangement (degrees of freedom and/or angle of pitch of shaft) for providing two orthogonal axes of rotation for said frame, wherein said frame is coupled to said arrangement (column 9 lines 55-60); and a movable member (bearing assembly), wherein: said movable member receives an end effector during a vascular access procedure (column 7 lines 49-55); said movable member moves along a linear path in a region defined by said frame (column 12 lines 45-52); and said linear path intersects said two orthogonal axes of rotation of said frame (yaw and pitch).

Referring to claim 20, Cunningham et al. discloses further comprising a force-feedback assembly, wherein said force-feedback assembly is coupled to said movable member (column 10 lines 3-46), and wherein said force-feedback assembly imparts a force that resists forward motion of said movable member by said end effector (column 10 lines 3-8).

Referring to claim 21, Cunningham et al. discloses wherein said force-feedback assembly comprises: a motor (electric motor); and a cable (offset pulley holds a rope or cable), wherein said cable is coupled to said motor (column 10 lines 21-26).

Referring to claim 22, Cunningham et al. discloses wherein said movable member

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(Friction wheels 84 & 85) includes a rolling-contact element (pulleys 100, 112, 115 holds a rope or cable), wherein said cable is coupled to said rolling-contact element (Figs. 4, 5B & the associated text).

Referring to claim 23, Cunningham et al. discloses further comprising a counterbalance (housing 50), wherein said counterbalance is coupled to said frame (outside of shaft 44).

Referring to claim 24, Cunningham et al. discloses pseudo skin (36); and a receiver (shaft 44) for coupling to an end effector, wherein: said receiver is disposed beneath said pseudo skin (From looking at Fig. 3, the shaft 44 appears to be below/within the case 32); and said receiver has no offset degrees of freedom (offset pulley 100).

Referring to claim 25, Cunningham et al. discloses wherein a magnetic force (column 10 lines 23-26) is used for coupling said end effector to said receiver.

Referring to claim 26, Cunningham et al. discloses wherein said end effector is selected from the group consisting of a catheter, a needle, and a combined catheter and needle (catheter needle assembly 47).

Referring to claim 27, Cunningham et al. discloses wherein said receiver (shaft 44) has three degrees of freedom (translation, pitch and yaw).

Referring to claim 28, Cunningham et al. discloses wherein two of said three degrees of freedom are rotational (yaw & pitch) and one of said three degrees of freedom is translational (translation).

Referring to claim 29, Cunningham et al. discloses wherein said receiver (shaft 44) comprises a movable member (column 13 lines 42-46), and wherein said movable

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member is movable along a linear path (bearings and one degree of freedom is linear).

Referring to claim 30, Cunningham et al. discloses wherein said receiver (shaft 44) comprises a movable member (column 13 lines 42-46), and wherein said movable member is physically adapted for rolling contact during movement (pulleys 100, 112 & 115).

Referring to claim 31, Cunningham et al. discloses wherein said receiver (shaft 44) is gravitationally balanced (gravity holds receiver in position).

Referring to claim 32, Cunningham et al. discloses further comprising said end effector (catheter 47), wherein, until coupled to said receiver (shaft 44) by a user, said end effector is disposed above said pseudo skin (Fig. 3 & the associated text).

Referring to claim 33, Cunningham et al. discloses wherein said receiver (shaft 44) further comprises: a movable member (pulleys 100, 112 & 115), wherein said movable member couples to said end effector (catheter 47); and a force-feedback assembly, wherein said force-feedback assembly is coupled to said movable element (column 10 lines 3-46 & column 12 lines 40-45).

Referring to claim 34, Cunningham et al. discloses pseudo skin (36); and a receiver (shaft 44) for coupling to an end effector, wherein: said receiver is disposed beneath said pseudo skin (From looking at Fig. 3, the shaft 44 appears to be below/within the case 32); and said receiver comprises a force-feedback assembly (column 10 lines 5-46).

Referring to claim 35, Cunningham et al. discloses wherein said receiver (shaft 44) further comprises a movable member (pulleys 100, 112 & 115), and wherein: said

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movable member is coupled to said force-feedback assembly (column 10 lines 3-46); said movable member couples to said end effector (catheter 47); when said movable member is coupled to said end effector, movement of said end effector causes said movable member to move (column 10 lines 3-46).

Referring to claim 36, Cunningham et al. discloses further comprising a data processing system, wherein, responsive to a signal from said data processing system (Fig. 1 & the associated text), said force-feedback assembly generates a force that opposes movement of said movable member and said end effector, in at least a first direction (column 10 lines 5-8).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham et al. in view of Lacey (WO 03/096307).

Referring to claim 18, Cunningham et al. discloses the apparatus of claim 17.

Cunningham et al. does not disclose further comprising pseudo skin, wherein said pseudo skin is substantially co-planar with a surface of said housing. However, Lacey teaches further comprising pseudo skin (skin-like panel 4), wherein said pseudo skin is substantially co-planar with a surface of said housing (plastics torso body form 3). It would have been obvious to one of ordinary skill in the art at the time the invention was

made to include wherein said pseudo skin is substantially co-planar with a surface of said housing, as disclosed by Lacey, incorporated into Cunningham et al. in order to extend as much as possible of the laparoscopic surgical instrument into the skin-like panel.

6. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lacey in view of Cunningham et al..

Referring to claim 37, An apparatus comprising: an end effector (laparoscopic instrument), wherein said end effector is a pseudo medical instrument; pseudo skin (skin-like 4), wherein said pseudo skin is physically adapted to enable said end effector to pass through it to a first region beneath said pseudo skin (Fig. 2 & the associated text); a data processing system (computer 6), wherein said data processing system: receives information indicative of a position of said end effector in said first region; determines a position of a virtual end effector in a virtual anatomy based on said received information (pages 6 & 7). *Lacey does not disclose determining a resistive force that would arise if said virtual end effector were present at said position in said virtual anatomy; and a force-feedback system, wherein said end effector is coupled to said force-feedback system when said end effector is in said first region, and wherein said force-feedback system generates said resistive force, and wherein said resistive force opposes movement of said end effector in said first region in at least some directions.* However, Cunningham et al. teaches determining a resistive force that would arise if said virtual end effector were present at said position in said virtual anatomy (column 7 lines 16-20); and a force-feedback system, wherein said end

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effector is coupled to said force-feedback system when said end effector is in said first region (column 10 lines 3-5), and wherein said force-feedback system generates said resistive force (column 10 lines 5-8), and wherein said resistive force opposes movement of said end effector in said first region in at least some directions (column 10 lines 3-46 & column 12 lines 40-52). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include resistive force and force feedback, as disclosed by Cunningham et al., incorporated into Lacey in order to provide a realistic feel to the simulation.

Citation of Pertinent Prior Art

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Pugh (U.S. Publication Number 2003/0031993) teaches a medical examination teaching and measurement system.

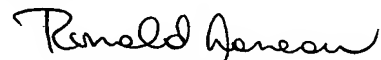
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kesha Frisby whose telephone number is 571-272-8774. The examiner can normally be reached on Mon. - Wed. 7-3pm & Thurs. - Fri. 7-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Xuan Thai can be reached on 571-272-7147. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Ronald Laneau
Primary Patent Examiner
Art Unit 3714

Kyf

Kyf 9/11/2007

9/14/07